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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2014-0531; FRL-9932-26]**

#### **Dimethomorph; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes, and removes tolerances for residues of dimethomorph in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is correcting the CAS name of dimethomorph in 40 CFR 180.493(a), 40 CFR 180.493(c), and 40 CFR 180.493(d).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0531, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0531 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0531, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8281) by BASF Corporation, P.O. Box 13528, Research Triangle Park, North Carolina, 27709. The petition requested that 40 CFR 180.493 be amended by establishing tolerances for residues of the fungicide, dimethomorph in or on strawberry at 1.0 parts per million (ppm) and removing the established tolerances for lettuce, head and lettuce, leaf at 10 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerance for residues of dimethomorph in or strawberry to 0.90 ppm and is correcting the CAS name of dimethomorph in 40 CFR 180.493(a), 40 CFR 180.493(c), and 40 CFR 180.493(d) to the following introductory tolerance expression text: 40 CFR 180.493(a): Tolerances are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity. 40 CFR 180.493(c): Tolerances with regional registrations are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity. 40 CFR 180.493(d): Tolerances are established for the indirect or inadvertent residues of the fungicide

dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

The reason for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dimethomorph including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with dimethomorph follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The target organ for dimethomorph is the liver in rats and dogs. No biologically significant effect was observed in the rat subchronic oral toxicity study while decreased body weight and increased incidence of arteritis in male rats and decreased body weights and increased incidence of "ground-glass" foci in livers of female rats were observed in the rat chronic toxicity study. In the dog subchronic oral toxicity study, decreased absolute and relative prostate weights, and slight liver effects were observed. No toxicity was observed at the limit dose in the rat 28-day dermal toxicity study. The developmental toxicity studies showed no increased sensitivity to offspring of either rats or rabbits as demonstrated by the no-observed-adverse-effect-levels (NOAELs) equal to or higher than those producing toxicity in the maternal animals. Likewise, in the 2-generation reproduction study, there was no toxicity to the offspring at any dose lower than that causing parental toxicity. There is no evidence that dimethomorph is a developmental, or reproductive toxicant, and it is not neurotoxic or immunotoxic.

The Agency classified dimethomorph as "not likely to be carcinogenic to humans" based upon lack of evidence of carcinogenicity in rats and mice and no evidence of mutagenicity. A quantitative cancer risk assessment is not necessary. Dimethomorph has low acute toxicity by the oral, dermal, or inhalation route of exposure (Toxicity Category III or IV). It is not an eye or skin irritant, and is not a skin sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by dimethomorph as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document

titled “Dimethomorph: Human Health Risk Assessment to Support Establishment of a Permanent Tolerance for Residues in/on Strawberry” at pages 29-32 in docket ID number EPA-HQ-OPP-2014-0531.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for dimethomorph used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Dimethomorph for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

Acute dietary (Females 13-50 years of age)	N/A (No appropriate endpoint was identified including developmental toxicity studies in rats and rabbits.)	N/A	N/A
Acute dietary (General population including infants and children)	LOAEL = 250 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF/ $UF_L = 10x$	Acute RfD = 0.25 mg/kg/day  aPAD = 0.25 mg/kg/day	Acute neurotoxicity study in rats  MRID 48980106  LOAEL = 250 mg/kg/day based on reduced motor activity and impairment of gait and rearing in both sexes.
Chronic dietary (All populations)	POD = 11 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.11 mg/kg/day  cPAD= 0.11 mg/kg/day	Co-critical chronic and carcinogenicity studies in rats MRID 42233912, 42233916  LOAEL = 46.3 mg/kg/day, based on decreased body weight and increases in liver lesions in female rats.
Incidental oral short-term	NOAEL= 15 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Subchronic feeding study in dogs  MRID 42233908  LOAEL = 43 mg/kg/day based on decreased absolute and relative prostate weights.
Dermal short- and intermediate-term	N/A (No toxicity was observed at the limit dose in a 28-day dermal toxicity study.  No quantitative risk assessment is necessary	N/A	N/A



	since no dermal or developmental toxicity concern.)		
Inhalation short- and intermediate-term	<p>Oral, NOAEL = 15 mg/kg/day</p> <p>(inhalation absorption factor = 100%)</p> <p><math>UF_A = 10x</math></p> <p><math>UF_H = 10x</math></p> <p><math>UF_{DB} = 10x</math></p>	LOC for MOE = 1000	<p>Subchronic feeding study in dogs</p> <p>MRID 42233908</p> <p>LOAEL = 43 mg/kg/day based on decreased absolute and relative prostate weights.</p>
Cancer (Oral, dermal, inhalation)	Classification: This chemical is classified as “not likely” to be a human carcinogen.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_{DB}$  = to account for the absence of data or other data deficiency.  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies).  $UF_L$  = use of a LOAEL to extrapolate a NOAEL.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to dimethomorph, EPA considered exposure under the petitioned-for tolerances as well as all existing dimethomorph tolerances in 40 CFR 180.493. EPA assessed dietary exposures from dimethomorph in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for dimethomorph. In estimating acute dietary exposure, EPA used food consumption

information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WEIA) 2003 – 2008. The acute analysis assumed 100% crop treated (CT), Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 3.16 default processing factors, and tolerance-level residues for all foods. Drinking water was incorporated directly into the dietary assessment using the surface water concentration and the FIRST (Food Quality Protection Act (FQPA) Index Reservoir Screening Tool) model.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WEIA 2003 – 2008. The chronic analysis assumed 100% CT, DEEM-FCID Version 3.16 default processing factors, and tolerance-level residues for all foods. Drinking water was incorporated directly into the dietary assessment using the surface water concentration and the FIRST model.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that dimethomorph does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use any anticipated residue or PCT information in the dietary assessment for dimethomorph.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for dimethomorph in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of dimethomorph. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on FIRST model for surface water and Pesticide Root Zone Model Ground Water (PRZM GW) for ground water, the estimated drinking water concentrations (EDWCs) of dimethomorph for acute exposures for non-cancer assessments are estimated to be 81.1 parts per billion (ppb) for surface water and 20.1 ppb for ground water; and for chronic exposures for non-cancer assessments are estimated to be 24.7 ppb for surface water and 18.8 ppb (post breakthrough avg. ppb) and 14.6 ppb (simulation avg. ppb) for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration of 81.1 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of 24.7 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Dimethomorph is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found dimethomorph to share a common mechanism of toxicity with any other substances, and dimethomorph does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that

dimethomorph does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicology data on dimethomorph provides no indication of enhanced sensitivity of infants and children based on the results from rat or rabbit developmental studies as well as a 2-generation rat reproduction study.

3. *Conclusion.* EPA has determined the 10X FQPA SF be retained for acute dietary exposure scenario for extrapolation of a NOAEL from a LOAEL. For other exposure scenarios, the FQPA SF is reduced to 1x since there is no evidence of increased qualitative or quantitative susceptibility in the young and exposure estimates are unlikely to underestimate risk.

The above decision is based on the following findings:

i. Although the toxicity database of dimethomorph is incomplete because a subchronic inhalation study is not available, the available toxicity database of dimethomorph, including developmental toxicity studies in rats and rabbits, a 2-generation reproduction study in rats,

acute and subchronic neurotoxicity study in rats, is adequate to characterize developmental and reproductive effects and to assess the qualitative or quantitative susceptibility in the young.

ii. In an acute neurotoxicity study, functional observational battery (FOB) findings and reduced motor activity were observed at  $\geq 250$  mg/kg on day 0 only. These findings were considered an impairment of the overall condition of the animals following a single gavage dose, rather than a direct neurotoxic effect of dimethomorph based on the absence of any neurohistopathological changes in the treated animals and the transient nature of the observed FOB and neurobehavioral assessments. In support of this conclusion, no neurotoxic effects were observed in rats fed dimethomorph up to the highest dose tested at 2,400 ppm (178/204 mg/kg/day for males/females, respectively) in a 90-day neurotoxicity study. Additionally, the toxicology database does not reveal evidence of neurotoxic clinical signs, changes in brain weight, or histopathology of the nervous system in any study with dimethomorph.

iii. There is no evidence that dimethomorph results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to dimethomorph in drinking water. These assessments will not underestimate the exposure and risks posed by dimethomorph.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to dimethomorph will occupy 39% of the aPAD for children 3 to 5 years of age, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to dimethomorph from food and water will utilize 26% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. There are no residential uses for dimethomorph.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short-term adverse effect was identified; however, dimethomorph is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for dimethomorph.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, dimethomorph is not registered for any use patterns that would result in intermediate-term

residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for dimethomorph.

5. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk was not calculated because dimethomorph was classified as “not likely to be carcinogenic to humans”.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to dimethomorph residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography with ultraviolet detection (HPLC/UV) method FAMS 002-04 and Method M 2577, a gas chromatographic (GC) method with nitrogen phosphorus detection (NPD)) are available to enforce the tolerance expression.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an

international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for dimethomorph in or on strawberry at 0.05 ppm. These MRLs are different than the tolerances established for dimethomorph in the United States. EPA is not proposing to harmonize the U.S. tolerance for residues in strawberry with the Codex due to different application rates (U.S. application rate, 219-237 gram active ingredient/hectare, and Codex countries' application rate, 150 gram active ingredient/hectare).

#### *C. Revisions to Petitioned-For Tolerances*

BASF proposed a tolerance of dimethomorph residues on strawberry at 1.0 ppm. BASF and EPA used the Organization for Economic Cooperation & Development (OECD) spreadsheet calculator and both determined from the data set that a tolerance of 0.90 ppm was the recommended OECD calculator spreadsheet output. However, BASF rounded that value to 1.0 ppm, while EPA's policy is to establish the tolerance at the OECD calculator output level without rounding; therefore, EPA is establishing a tolerance on strawberry at 0.90 ppm. EPA established the tolerance for leafy vegetables (except brassica) crop group 4 in the **Federal Register** on May 4, 2012 under docket ID number EPA-HQ-OPP-2011-0388. In this ruling, the tolerance for vegetable, leafy, except brassica, group 4 was established at 30.0 ppm. According to 40 CFR 180.493, the individual tolerances for lettuce, head and lettuce, leaf, both at 10.0 ppm, were not removed. Based upon the previous explanation, EPA is removing the tolerances for lettuce, head at 10.0 ppm and lettuce, leaf at 10.0 ppm.

EPA is correcting the CAS name of dimethomorph in 40 CFR 180.493(a),



40 CFR 180.493(c), and 40 CFR 180.493(d). The CAS name of dimethomorph is currently incorrect (currently is listed as the International Union of Pure and Applied Chemistry (IUPAC) name (E,Z)-4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl) acryloyl]morpholine, and is being revised to the correct CAS name 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine)).

## **V. Conclusion**

Therefore, EPA is establishing a tolerance for residues of the fungicide, dimethomorph in or on strawberry at 0.90 ppm and removing the established tolerances for lettuce, head and lettuce leaf at 10 ppm. EPA is correcting the CAS name of dimethomorph in 40 CFR 180.493(a), 40 CFR 180.493(c), and 40 CFR 180.493(d) to the following tolerance expressions:

40 CFR 180.493(a): Tolerances are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

40 CFR 180.493(c): Tolerances with regional registrations are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

40 CFR 180.493(d): Tolerances are established for the indirect or inadvertent residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in

the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section

408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

## **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 10, 2015.

Susan Lewis,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.493:

- a. Revise the introductory text of paragraph (a).

- b. Remove the entries in the table in paragraph (a) for “Lettuce, head”, and “Lettuce leaf”.

- c. Add alphabetically the entry for “Strawberry” to the table in paragraph (a).

- d. Revise the introductory text of paragraphs (c) and (d).

The additions and revisions read as follows:

**§180.493 Dimethomorph; tolerances for residues.**

(a) \* \* \*

Tolerances are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodities.

Commodity	Parts per million
* * *	* * *
Strawberry	0.90
* * *	* * *

\* \* \* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-

dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

\* \* \* \* \*

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent residues of the fungicide dimethomorph, 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only dimethomorph in or on the commodity.

\* \* \* \* \*